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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,401	09/12/2005	Irene Bozzoni	2520-1050	2717
<div>466 7590 01/08/2008</div> <div>YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202</div>				
			EXAMINER RAMIREZ, DELIA M	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 01/08/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,401

Applicant(s)

BOZZONI ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-21, 35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2007 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Claims 18-21 and 35-36 are pending.

Applicant's amendment of claims 18-21, addition of claims 35-36, submission of a new CRF sequence listing and amendments to the specification and the figures, as submitted in a communication filed on 10/10/2007 are acknowledged.

Amended claim 18 and new claim 36 are directed to a non-elected invention, i.e., a polypeptide encoded by the polynucleotide of SEQ ID NO: 1. According to the specification of the instant application, the polypeptide encoded by the polynucleotide of SEQ ID NO: 1 is the polypeptide of SEQ ID NO: 2. Thus, amended claim 18 and new claim 36 belong to non-elected original Group II as set forth in the restriction requirement mailed on 1/30/2007. Since Applicant has received an action on the merits for the originally presented invention (i.e., a nucleic acid), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 18 and 36 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 19-21 and new claim 35 are directed to the elected invention and are being examined.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

1. It is noted that the new sequence listing provides an additional sequence (i.e., SEQ ID NO: 10). However no explanation as to why a new sequence has been introduced is given in the response. Upon a cursory review of the amendments made to the specification, it has been noted that SEQ ID NO: 10 appears to be a sequence which is disclosed in Figure 6. Clarification is required.
2. The specification is objected to as containing new matter. This objection is necessitated by Applicant's response to a previous objection made by the Examiner regarding the discrepancies between

the sequences shown in Figure 4 and the sequence listing, as well as an amendment to the sequence disclosed regarding oligonucleotide P2 as shown in the specification on page 8.

3. As previously indicated in the Non Final action mailed on 4/10/2007, a cursory review of Figure 4 showed that the amino acid sequence of XendoU does not match SEQ ID NO: 2 as provided in the CRF and paper sequence listing of 1/6/2005 because (1) the residue at position 161 in Figure 4 is an E (glutamic acid) residue whereas the residue at position 161 of SEQ ID NO: 2 as shown in the sequence listing is an R residue, and (2) SEQ ID NO: 1 as provided in the CRF and paper sequence listing has 1265 nucleotides whereas the sequence on Figure 4 has 1268 nucleotides.

4. In response to the previous objection, Applicant indicates that the new sequence listing shows an E amino acid at position 161, as shown in Figure 4. However, no explanation as to why Figure 4 shows a nucleic acid which is 1268 nucleotides and SEQ ID NO: 1 has only 1265 has been presented has been provided. The new CRF sequence listing filed on 10/10/2007 shows SEQ ID NO: 1 as having 1265 nucleotides. No explanation as to why there are 3 nucleotides missing in the polynucleotide encoding the polypeptide of SEQ ID NO: 2 has been given. A cursory review of Figure 4 as shown in the foreign priority document, Figure 4 and the sequence listing as shown in the WIPO document, and Figure 4 as disclosed in the specification as originally filed show that there is support for a polynucleotide comprising 1268 nucleotides, wherein said polynucleotide comprises a sequence which contains the first 987 nucleotides of SEQ ID NO: 1, followed by nucleotides CAA, followed by nucleotides 988-1265 of SEQ ID NO: 1. However, neither the priority document or the WIPO document provide support for a polynucleotide which comprises or consists of SEQ ID NO: 1. Moreover, a cursory review of the sequence listing filed with the WIPO document shows that SEQ ID NO: 4 matches the sequence of P2 disclosed in the specification, page 8, as originally filed, but does not match the amended P2 sequence shown on page 8 of the specification. No explanation as to why the last nucleotide has been changed

from a T to a G has been provided, or where one could find support for this change. Therefore, Applicant is required to cancel the new matter in the reply to this Office Action.

Drawings

5. The drawing submitted on 10/10/2007 is objected to for the following reasons. P2 as disclosed in the specification as originally filed (page 8, line 26) has a sequence which ends with a T base. P2 as shown in amended Figure 3a shows a sequence which ends with a G base. Correction is required.

Claim Objections

6. Claims 20-21 are objected to due to the recitation of "nucleic acid in prokaryotes/eukaryotes according to claim 19". As written, the term "claim 19" can lead to confusion because it may appear as if it refers to the prokaryotes/eukaryotes and not the nucleic acid. It is suggested the term be amended to recite "nucleic acid of claim 19 in prokaryotes/eukaryotes" to clearly indicate that the term "claim 19" refers to the nucleic acid. Appropriate correction is required.

Claim Rejections - 35 USC § 112, First Paragraph

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 19-21 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection necessitated by Applicant's response.

Claims 19-21 and 35 are directed to a nucleic acid comprising/consisting of SEQ ID NO:1, and vectors comprising a nucleic acid comprising SEQ ID NO:1. As indicated above regarding the objection to the specification, while there is support for a polynucleotide comprising 1268 nucleotides, wherein said polynucleotide comprises a sequence which contains the first 987 nucleotides of SEQ ID NO: 1, followed by nucleotides CAA, followed by nucleotides 988-1265 of SEQ ID NO: 1, neither the priority document or the WIPO document provide support for a polynucleotide which comprises or consists of SEQ ID NO: 1, or vectors comprising the polynucleotide of SEQ ID NO: 1. Thus, there is no indication that a polynucleotide comprising SEQ ID NO: 1 was within the scope of the invention as conceived by Applicants at the time the application was filed. Accordingly, Applicants are required to cancel the new matter in response to this Office Action.

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
10. Claims 19-20 were rejected under 35 U.S.C. 102(a) as being anticipated by Laneve et al. (J. Biol. Chem. 278(15):13026-13012, April 2003). This rejection has been discussed at length in the Non Final action mailed on 4/10/2007.
11. In view of the fact that Laneve et al. do not teach a nucleic acid comprising SEQ ID NO: 1 and Applicant's amendment of claim 19, which is now directed to a nucleic acid comprising SEQ ID NO: 1, this rejection is hereby withdrawn.
12. Claim 19 was rejected under 35 U.S.C. 102(b) as being anticipated by Laneve, P. (Purificazione e caratterizzazione di una nuova attivita endoribonucleolitica coinvolta nella biosintesi dei piccolo RNA

nucleolari in *X. laevis*, Thesis, 2001; cited in the IDS) as evidenced by GenBank accession number AJ507315 (cited in the IDS).

13. In view of the fact that Laneve does not teach a polynucleotide comprising SEQ ID NO: 1 and claim 19 as amended is now directed to a nucleic acid comprising SEQ ID NO: 1, this rejection is hereby withdrawn.

14. It is noted that if SEQ ID NO: 1 is amended to include nucleotides CAA between nucleotides 987-988 of SEQ ID NO: 1, this rejection will be reintroduced because such nucleic acid is identical to the polynucleotide of Laneve (i.e., nucleotides 1-987 of SEQ ID NO: 1, followed by CAA, followed by nucleotides 988-1268 of SEQ ID NO: 1). Applicant is reminded that this rejection is based on the teachings of the thesis by Laneve as evidenced by GenBank entry AJ507315. Thus, the 102(b) date used is that of the thesis (2001) and not that of the GenBank entry.

Claim Rejections - 35 USC § 103

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. Claim 21 was rejected under 35 U.S.C. 103(a) as being unpatentable over Laneve et al. (J. Biol. Chem. 278(15):13026-13012, April 2003).

17. Claims 20-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Laneve, P. (Purificazione e caratterizzazione di una nuova attivita endoribonucleolitica coinvolta nella biosintesi dei piccolo RNA nucleolari in *X. laevis*, Thesis, 2001; cited in the IDS).

18. In view of the fact that claim 19, from which claims 20-21 depend, now requires the nucleic acid to comprise SEQ ID NO: 1 and neither Laneve et al. (J. Biol. Chem. 278(15):13026-13012, April 2003) nor Laneve, P. (Purificazione e caratterizzazione di una nuova attivita endoribonucleolitica coinvolta nella

biosintesi dei piccolo RNA nucleolari in *X. laevis*, Thesis, 2001) teach or suggest SEQ ID NO: 1 as currently presented, these rejections are hereby withdrawn.

19. It is noted that if SEQ ID NO: 1 is amended to include nucleotides CAA between nucleotides 987-988 of SEQ ID NO: 1, the rejection of claims 20-21 over Laneve, P. (Purificazione e caratterizzazione di una nuova attivita endoribonucleolitica coinvolta nella biosintesi dei piccolo RNA nucleolari in *X. laevis*, Thesis, 2001) will be reintroduced because such nucleic acid is identical to the polynucleotide of Laneve (i.e., nucleotides 1-987 of SEQ ID NO: 1, followed by CAA, followed by nucleotides 988-1268 of SEQ ID NO: 1).

Conclusion

20. No claim is in condition for allowance.

21. Applicant's amendment/response necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Application/Control Number:
10/520,401
Art Unit: 1652

Page 8

Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Primary Patent Examiner
Art Unit 1652

DR
January 4, 2008